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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/698,354      | 10/30/2003  | David James Rawson   | PC25373A            | 1622             |

7590 05/17/2006

Warner-Lambert Company LLC  
2800 Plymouth Road  
Ann Arbor, MI 48105

EXAMINER

JONES, DWAYNE C

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1614

DATE MAILED: 05/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/698,354

**Applicant(s)**

RAWSON, DAVID JAMES

**Examiner**

Dwayne C. Jones

**Art Unit**

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24FEB2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 9-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 3/2/4; 3/22/4; 6/4/4
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: IDS 6/4/4

## **DETAILED ACTION**

### ***Status of Claims***

1. Claims 1-13 are pending.
2. Claims 9-13 are elected and rejected.
3. Claims 1-8 are non-elected and withdrawn from consideration.

### ***Priority***

4. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### ***Election/Restrictions***

5. Applicant's election with traverse of Group II, corresponding to claims 9-13, in the reply filed on February 24, 2006 is acknowledged. The traversal is on the ground(s) that the two groups should be searched together since a search for the compounds would identify art related to their uses. This is not found persuasive because the process of using the process claims, such as claim 1, could be used by a materially and structurally different and distinct product, namely gabapentin.

The requirement is still deemed proper and is therefore made FINAL.

### ***Information Disclosure Statement***

6. The information disclosure statements filed on March 2, 2004 (4 sheets); March 22, 2004 (1 sheet); and June 4, 2004 (1 sheet) have been reviewed and considered, see enclosed copies of PTO FORMS 1449.

***Specification***

7. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 11-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims are directed to pharmaceutical composition claims however these claims currently have dependency on claims that are (1) withdrawn and (2) claims that are not composition claims but rather methods of use claims. Consequently, these anomalies render the claims vague and indefinite to the skilled artisan.

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

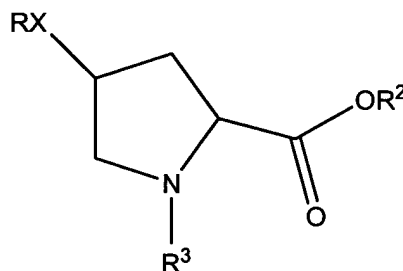
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claims 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kyle et al. of U.S. Patent No. 5,385,889. Kyle et al. of proline compounds (intermediates) (see column 6, lines 34-44 and column 20, lines 35-61) of the following formula:



where the variable of R is aryl or a substituted aryl group, and an arylalkyl group, X is O or S, (see column 20, lines 49, 51, and 52), R<sup>2</sup> and R<sup>3</sup> are H is (see column 20, lines 56 and 59). In addition, Kyle et al. teach that the term “substituted aryl” embraces an aromatic ring, such as phenyl, with substituents, namely nitro, halogens, (see from column 20, line 66 to column 21, line 2). In fact, Kyle et al. teach of that the variable R can be represented by nitrophenyl, chlorophenyl, 4-methylphenyl, (see column 6, lines

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9-13). Clearly, the teachings of Kyle et al. provide the skilled artisan with motivation to select other substituents, such as alkoxy, thioalkoxy, amino, dialkylamino, halogenated alkyl groups, that would not materially affect the properties of the aromatic ring moiety by providing the skilled artisan with examples of various substituents on an aromatic ring. The preparation of compounds for administration along with pharmaceutical acceptable salts, excipients, diluents, and carriers, in pharmaceutical compounds for administration in various formulations may be performed in a variety of ways that are known to the skilled artisan, (see columns 23-24). Moreover, Kyle et al. teach that of combining other therapeutic agents, such as antioxidants and bacteriostats, (see column 23, lines 48-51). The determination of a dosage, pharmaceutical preparation, and modes and methods of administration having the optimum therapeutic index is well within the level of one having ordinary skill in the art, and the artisan would be motivated to determine optimum amounts, acceptable pharmaceutical salts, excipients, carriers, as well as modes and methods of administration in order to get the maximum effect of the drug while minimizing adverse and/or unwanted side-effects.

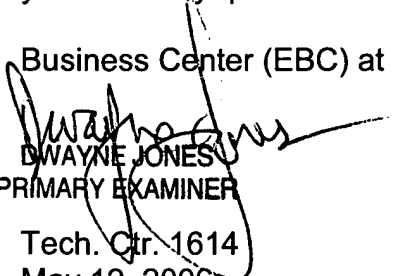
Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (571) 272-0578. The examiner can normally be reached on Mondays, Tuesdays, Wednesdays, and Fridays from 8:30 am to 6:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, may be reached at (571) 272-0718. The official fax No. for correspondence is (571)-273-8300.

Also, please note that U.S. patents and U.S. patent application publications are no longer supplied with Office actions. Accordingly, the cited U.S. patents and patent application publications are available for download via the Office's PAIR, see <http://pair-direct.uspto.gov>. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site ([www.uspto.gov](http://www.uspto.gov)), from the Office of Public Records and from commercial sources.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications may be obtained from Private PAIR only. For more information about PAIR system, see <http://pair-direct.uspto.gov> Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 1-866-217-9197 (toll free).

  
DWAYNE JONES  
PRIMARY EXAMINER

Tech. Ctr. 1614  
May 12, 2006